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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/068,447 | 02/06/2002 | Kurt R. Gehlsen | MAXIM.073DVIC1 | 1030 |

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EXAMINER

BERKO, RETFORD O

| ART UNIT | PAPER NUMBER |
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1618

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/068,447 | Applicant(s) GEHLSSEN, KURT R. | |
| | Examiner Retford Berko | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-30,32 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30,32 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgement: Applicant's amendment filed December 13, 2004 is acknowledged.

Status of Claims

The status of the claims is as follows:

- a. Claims 1-25 were cancelled in a previous amendment
- b. Claims 31 and 33-44 are cancelled in amendment filed 12/13/04
- c. Claims 26-30, 32 and 45 are pending in the application following the 12/13/04 amendment.

Withdrawal of Claims Rejections:

- a. The rejection of claims 26-32 and 35-37 under 35 USC 102(b) as anticipated by Hellstrand et al (WO 97/42968) is withdrawn in view of applicant's remarks and arguments.
- b. The rejection of claims 26, 29 and 34 under 35 USC 102(b) as anticipated by Jack et al (WO 95/23601) is withdrawn in view of applicant's remarks and arguments.
- c. Because applicant has cancelled the claims without prejudice, this withdrawal of claims rejections do not affect claims cancelled by applicant---it is a moot issue.

Claim Rejections-35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title; if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-30, 32 and 45 remain rejected under 35 USC 103(a) as being unpatentable over Hellstrand et al (WO 97/42968) in view of Bruce et al (WO '95/23601) further in view of Bathurst et al (US6, 004, 579; 102(e) date of Sep 4, 1997).

The claims are directed toward a method of making a cosmetic composition for topically delivering a compound that inhibits production of reactive oxygen metabolites (ROMs); comprising providing a cosmetically acceptable carrier and a compound selected from a group consisting of histamine or histamine salts. The claims are also directed toward the method wherein the compound inhibits production of ROMs, and the histamine -releasing compound is retinoic acid, IL-3; allergen and wherein the method produces a composition that is a lipstick, a shampoo or a spray. The claims are further drawn toward the composition formed by the method wherein said composition has a cosmetic carrier and the compound is a histamine or its salt, that the composition comprises of colorant (FDA red dye or Yellow No. 5); contains a fragrance; moisturizer and sunscreen and soap.

Hellstrand et al (Patent WO '968) and Bruce (Patent WO '601) have been discussed. Neither patent discloses a method for making the composition wherein histamine phosphate is the active ingredient and is also formulated to contain fragrance and colorants.

Bathurst (Patent '579) disclose a method of making topical composition for treatment of dermatological conditions; said composition formulated as liquids, creams, lotion, ointment, suntan lotion, sunscreen et and (col 10, lin 60-65, continuing to col 11, lin 1-10). According to the disclosure in Patent '579, the formulations are for treating dermatologic conditions (col 14, lin 55-60 and col 19, lin 10-14).

One of ordinary skill in the art would be motivated to make a dermatologic composition for topical application as disclosed in the cited prior art and include cosmetically acceptable carrier and ingredients as fragrances and colorants. One of ordinary skill would expect to obtain a cosmetic composition such as creams, gels, lotions and sunscreens that upon topical application allow the skin to heal and resist cell damage as well as restore normal skin function. The motivation to combine the references cited lies in the reasonable expectation for success in achieving the beneficial effects of the composition in treating various dermatological conditions as disclosed by Bathurst et al in Patent '579 (col 14, lin 42-60). Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

Response To Arguments

Applicant's remarks and arguments have been considered but they are found unpersuasive:

Applicant argues that there is a difference between a traditional therapeutic composition and a cosmetic composition when considering the aesthetics of disease treatment, that cosmetic compositions focus on both treatment of disease and patient's aesthetic concerns and that prior to the instant claims, methods for making cosmetic compositions comprising histamine or histamine-related compound for making cosmetic formulations was not contemplated.

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Furthermore, applicant contends that neither WO '968 nor WO '601 considered, much less addressed, a patient's aesthetic concerns and thus neither provides a teaching or suggestion for a method for making cosmetic compositions comprising compounds that inhibit the production and release of enzymatically produced ROMs.

In response, WO '968 discloses composition for topical application and treatment of skin diseases and conditions including sunburn, thermal burn and other lesions (page 9, lin 26-33; page 11, lin 3-20; page 13, lin 27-32; page 28, lin 20-30; page 49, lin 1-30 continuing to page 50, lin 1-5 and page 71-73). These topical applications of the composition are suggestive of cosmetic use.

Applicant argues that there is no teaching or suggestion in the Patent '579 to use cosmetic carriers with compositions other than phospholipid-containing compositions, that there is no reasonable expectation of success derived from the cited reference in practicing the claimed invention as both WO '968 and WO '601 are completely silent as to the benefits of administering compounds in cosmetically acceptable carriers.

In response, the dermal application of the composition and method disclosed in WO '968 has been indicated above. Further, Patent '579 discloses cosmetic products, topical applications and treatment of dermatological conditions (col 9, lin 1-25, col 10, lin 1-5, lin 57-67, col 14, lin 45-60 and col 19-20).

Applicant asserts that neither prior art reference alone or in combination disclose the application of a composition comprising histamine, histamine dihydrochloride, histamine diphosphate, other histamine salts, esters, prodrugs, histamine-receptor agonists, serotonin, and

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5HT agonists in a cosmetically acceptable carrier and it not obvious to provide the disclosed compounds in cosmetically acceptable carriers based upon WO '601 and '579 patent.

In response, examiner discussed the disclosures of WO'969, WO '601 and Patent '578. Despite applicant's assertions, the obviousness of making a cosmetic composition as in the instant claims is established given the disclosures in the prior art as one of ordinary skill in the art would be motivated to make a dermatologic composition for topical application and reasonably expect to obtain a cosmetic composition such as creams, gels, lotions and sunscreens. Conclusion: No claims are allowed.

The following prior art is made of record as pertinent to applicant's claims although the reference is not relied upon in the present office action for the rejection of claims. The reference discloses the use of specific polymers cited in applicant's specification as examples of the current invention (col 14, lin20-65; continuing to col15, lin 1-35; compare with specification at pages 19-21). The reference is not used because it does not teach all the requirements of the claims as modified.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Respectfully,

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600